

## **REMARKS/ARGUMENTS**

### **A. Status of the Claims**

Claims 1-6 are pending.

Claims 1, 2, 4 and 5 were amended. Support for these amendments can be found throughout the specification and in original claims 1, 2, 4, and 5. Additional support for the amendments to claim 4 can be found in paragraph [0033] of the present specification.

New claims 7-12 were added. Support for claim 7 can be found in original claims 1 and 2. Support for claim 8 can be found in original claims 1 and 6. Support for claim 9-12 can be found throughout the specification, e.g., in paragraphs [0016], [0021]-[0023], and in the original claims 1, 2 and 6.

After claims additions, claims 1-12 will be pending. It is respectfully submitted that no new matter was added by virtue of this amendment.

### **B. Claim Informalities**

In the Office Action, the Examiner requested that “a” (before “toothpaste”) in claim 1 be changed to “as.” In response, Applicants submit that amended claim 1 recites “as” before the term “toothpaste.”

In the Office Action, the Examiner requested that “an” (before “active”) in claim 2 be deleted. In response, Applicants submit that amended claim 2 does not recite “an” before the term “active.”

In the Office Action, the Examiner asserted that claim 4 should recite “N-acetyl-5-methoxytripamine,” instead of “N-acetyl-5-metoxitripamine.” (emphasis added). In response, Applicants submit that amended claim 4 recites “N-acetyl-5-methoxytripamine.”

In the Office Action, the Examiner asserted that claim 5 should recite “hydroquinone.” In response, Applicants submit that amended claim 5, recites “hydroquinone.”

### C. Claim Objection

In the Office Action, the Examiner objected to claim 4, for being in an improper dependent form, allegedly as failing to limit the subject matter of a previous claim.

In response, Applicants submit that amended claim 4 recites: “[t]he oral hygiene product according to claim 1, wherein the melatonin is a synthetic N-acetyl-5-methoxytryptamine.” (emphasis added). Applicants further submit that amended claim 4 is in proper dependent form and request that the objection be withdrawn.

### D. Indefiniteness Rejection

Claim 1-6 were rejected under 35 U.S.C. §112, as being indefinite. The Examiner stated that, in claim 1, “the weight percentage value is unclear because the basis for its determination has not been set forth.” The Examiner further stated that “[i]n order to overcome this ground of rejection the examiner recommends inserting after “5%” the phrase --- of the oral hygiene product.”

Applicants respectfully submit that amended claim 1 recites “...melatonin in a proportion of from more than 2% to 5% of the oral hygiene product by weight.” Accordingly, Applicants submit that the Examiner’s rejection has been overcome, and request withdrawal of the rejection.

### E. Anticipation Rejections

#### 1. U.S. Patent No. 6,998,112 to Zuckerman

Claims 1, 3, and 4 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,998,112 to Zuckerman (“the Zuckerman patent). The Examiner stated that the Zuckerman patent “discloses toothpastes comprising 0.2 to 2 percent by weight of melatonin.”

Applicants submit that claim 1 recites in part an oral hygiene product comprising “...melatonin in a proportion of from more than 2% to 5% of the oral hygiene product by weight.”

Applicants further submit that the Zuckerman patent does not teach an oral hygiene product comprising more than 2% of melatonin by weight because the Zuckerman patent states that “[m]elatonin comprises substantially 0.25% to 2%” of the products described therein. See column 5, lines 25-26. Accordingly, Applicants respectfully request that the anticipation rejection of claim 1, and claims 3 and 4 which both depend on claim 1, be withdrawn.

With regard to new claim 7, Applicants note that claim 7 includes the limitations of original claim 2, which was not included in the present rejection. Accordingly, Applicants submit that the Zuckerman patent does not anticipate claim 7.

With regard to new claim 8, Applicants note that claim 8 includes the limitations of original claim 6, which was not included in the present rejection. Accordingly, Applicants submit that the Zuckerman patent does not anticipate claim 8.

With regard to new claims 9-12, Applicants submit that the Zuckerman patent does not teach a method of treatment of oral illness comprising “administering to a damaged mouth tissue of a human or an animal an oral hygiene product ...” as recited in claim 9. Applicants respectfully note that melatonin is included into the toothpastes described in the Zuckerman patent as “a sleep inducing ...hormone,” and not for the “treatment of oral illness” as recited in claim 9. See e.g., Abstract. Accordingly, Applicants submit that claim 9, and claims 10-12 which all depend on claim 9, are novel over the Zuckerman patent.

## 2. U.S. Patent No. 6,200,550 to Masterson

Claims 1, 3, 4, and 6 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,200,550 to Masterson “the Masterson patent.” The Examiner asserted that the Masterson patent “discloses toothpastes comprising 0.2 to 2 percent by weight of melatonin (column 7, line 2).”

Applicants respectfully note that the passage referred to by the Examiner states:

*Tocopheryl acetate and  $\beta$ -carotene are most preferred for use in the present invention and are used at a concentration of between about 0.1% to about 20%, preferably they are used between about 0.2% and about 2% by weight.*

See the Masterson patent, column 7, lines 3-6.

Accordingly, Applicants submit that the weight percentage range recited in this passage is for either Tocopheryl acetate or  $\beta$ -carotene, and not for melatonin. Applicants further submit that the Masterson patent does not teach an oral hygiene product comprising "...melatonin in a proportion of from more than 2% to 5% of the oral hygiene product by weight," as recited in claim 1. Accordingly, Applicants request withdrawal of the anticipation rejection over the Masterson patent of claim 1, and claims 3 and 4 which both depend on claim 1.

With regard to new claim 7, Applicants respectfully note that claim 7 includes the limitations of original claim 2, which was not included in the present rejection. Accordingly, Applicants submit that the Masterson patent does not anticipate claim 7.

With regard to new claim 8, Applicants note that claim 8 includes the limitations of original claim 6, which was not included in the present rejection. Accordingly, Applicants submit that the Masterson patent does not anticipate claim 8.

With regard to new claims 9-12, Applicants respectfully submit that the Masterson patent does not teach a method of treatment of oral illness "comprising administering to a damaged mouth tissue ... melatonin in a proportion of 0.1% to 5% of the product by weight," as recited in claim 9. Accordingly, Applicants submit that claim 9, and claims 10-12 which all depend on claim 9, are novel over the Masterson patent.

#### F. Obviousness Rejection

In the Office Action, claims 1-6 were rejected under 35 U.S.C. § 103 (a) over U.S. Patent No. 6,509,007 to Rajaiah et al. ("the Rajaiah patent") in view of the Masterson patent. The Examiner stated that the primary the Rajaiah patent "does not specifically disclose the relative

proportion of the antioxidants...". The Examiner, then, relied on the Masterson patent to cure this deficiency.

Applicants respectfully submit that the Masterson patent cannot cure this deficiency in the Rajaiah et al., as the Masterson patent does not teach or suggest an oral hygiene product comprising "...melatonin in a proportion of from more than 2% to 5% of the oral hygiene product by weight," as recited in claim 1, for the reasons articulated above.

Applicants further submit that one skilled in the art would not be motivated to combine the Rajaiah patent and the Masterson patent, at the very least, because the main ingredient in the Rajaiah has a different mechanism of action than the main ingredient in the Masterson patent, and because the main ingredient of the Rajaiah patent may interfere with the action of the main ingredient of the Masterson patent. Applicants submit that the main ingredient in the Rajaiah patent is polybutene. See, e.g., Abstract. The compositions described in the Rajaiah patent "effectively coat and protect the teeth from buildup of plaque and other debris." See, e.g., column 1, lines 51-53. In contrast, the main ingredient in the Masterson patent is Coenzyme Q10, which is "a potent water insoluble antioxidant that is involved in electron transport and oxidative phosphorylation." See e.g., Column 1, lines 5-11. Applicants submit that the coating on teeth created by the products described in the Rajaiah patent may interfere with the availability and local effects of the antioxidant Coenzyme Q10 of the Masterson patent. Applicants note that the Masterson patent states that "the availability of an active ingredient is particularly important." See e.g., column 1, lines 24-25. Accordingly, Applicants submit one skilled in the art would not be motivated to combine the Rajaiah patent and the Masterson patent.

Accordingly, Applicants respectfully request that the obviousness rejection over claim 1, and claims 2-6, which all depend on claim 1, be withdrawn.

**CONCLUSION**

An early and favorable action of the merits is earnestly solicited.

Respectfully submitted,

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